

WHAT IS CLAIMED IS:

1. A pharmaceutical formulation comprising  
a biologically active agent and methionine, wherein  
5 said formulation demonstrates improved stability, and  
wherein said formulation does not contain human serum  
albumin.

2. A formulation according to Claim 1  
10 wherein said methionine is present in a concentration  
of about 0.5mM-50mM.

3. A formulation according to Claim 2  
wherein said active agent is selected from the group  
15 consisting of peptides, small molecules, carbohydrates,  
nucleic acids, lipids, proteins, and analogs thereof.

4. A formulation according to Claim 3  
wherein said active ingredient is a protein.  
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5. A formulation according to Claim 4  
wherein said protein is erythropoietin (EPO).

6. A formulation according to Claim 5  
25 wherein said EPO has an amino acid sequence as depicted  
in SEQ ID NO:1.

7. A formulation according to Claim 6  
further comprising a pH buffering agent which provides  
30 a pH range of about 5 to about 7.

8. A formulation according to Claim 7  
further comprising a stabilizing amount of a sorbitan  
mono-9-octadecenoate poly(oxy-1,2-ethanediyl)

derivative which is present in a concentration of about 0.001% to 0.1% (w/v).

9. A formulation according to Claim 4  
5 wherein said protein is novel erythropoiesis stimulating protein (NESP) or a chemically modified form thereof.

10. A formulation according to Claim 9  
10 wherein said NESP has an amino acid sequence as depicted in SEQ ID NO:2.

11. A formulation according to Claim 10  
15 further comprising a pH buffering agent which provides a pH range of about 5 to about 7.

12. A formulation according to Claim 11  
further comprising a stabilizing amount of a sorbitan mono-9-octadecenoate poly(oxy-1,2-ethanediyl)  
20 derivative which is present in a concentration of about 0.001% to 0.1% (w/v).

13. A pharmaceutical multi-dose formulation comprising a biologically active agent, a preservative,  
25 and methionine, wherein said formulation demonstrates improved stability, and wherein said formulation does not contain human serum albumin.

14. A formulation according to Claim 13  
30 wherein said methionine is present in a concentration of about 0.5mM to 50mM.

15. A formulation according to Claim 14 wherein said active agent is selected from the group

consisting of peptides, small molecules, carbohydrates, nucleic acids, lipids, proteins, and analogs thereof.

16. A formulation according to Claim 15  
5 wherein said active ingredient is a protein.

17. A formulation according to Claim 16  
wherein said protein is erythropoietin (EPO).

10 18. A formulation according to Claim 17  
wherein said EPO has an amino acid sequence as depicted  
in SEQ ID NO:1.

15 19. A formulation according to Claim 18  
wherein said preservative is benzyl alcohol which is  
present in a concentration of about 0% to 2% (w/v).

20 20. A formulation according to Claim 19  
further comprising a pH buffering agent which provides  
a pH range of about 5 to about 7.

21. A formulation according to Claim 20  
further comprising a stabilizing amount of a sorbitan  
mono-9-octadecenoate poly(oxy-1,2-ethanediyl)  
25 derivative which is present in a concentration of about  
0.001% to 0.1% (w/v).

22. A formulation according to Claim 16  
wherein said protein is novel erythropoiesis  
30 stimulating protein (NESP) or a chemically modified  
form thereof.

23. A formulation according to Claim 22  
wherein said NESP has an amino acid sequence as  
35 depicted in SEQ ID NO:2.

24. A formulation according to Claim 23 wherein said preservative is benzyl alcohol which is present in a concentration of about 0% to 2% (w/v).

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25. A formulation according to Claim 24 further comprising a pH buffering agent which provides a pH range of about 5 to about 7.

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26. A formulation according to Claim 25 further comprising a stabilizing amount of a sorbitan mono-9-octadecenoate poly(oxy-1,2-ethanediyl) derivative which is present in a concentration of about 0.001% to 0.1% (w/v).

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27. A method of stabilizing a pharmaceutical composition of a biologically active agent which comprises adding methionine to said composition in amount sufficient to inhibit oxidation of methionine residues in the amino acid sequence of said biologically active agents; wherein said formulation does not contain human serum albumin.

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